

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 2003 list were published in the Federal Register in June 2003.

### New Approvals

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#### NADA Number: 141-193

Trade Name: Zubrin™ Rapidly-Disintegrating Tablets  
Ingredients: Tepoxalin  
Sponsor: Schering-Plough Animal Health Corp.  
Approval Date: March 31, 2003  
Status: Prescription only  
Route: Oral  
Species: Dogs  
Drug Form: Tablet  
Concentration: 30, 50, 100, or 200 milligrams per tablet  
Indications: For the control of pain and inflammation associated with osteoarthritis.  
Patent Number: 5,164,381      Expiration date: November 17, 2009  
4,826,868      May 29, 2006  
Exclusivity: 5 years

21CFR 520.2340

#### NADA Number: 141-214

Trade Name: Zimecterin® Gold Paste  
Ingredients: Ivermectin and praziquantel  
Sponsor: Merial Ltd.  
Approval Date: April 17, 2003  
Status: Over-the-counter  
Route: Oral  
Species: Horses  
Drug Form: Paste  
Concentration: 1.55% ivermectin and 7.75% praziquantel  
Indications: For treatment and control of the following parasites:  
Tapeworms: *Anoplocephala perfoliata*  
Large strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *Strongylus edentatus*, (also tissue stages), *Strongylus equinus*; *Triodontophorus* spp. including: *T. brevicauda*, *T. serratus*; *Craterostomum acuticaudatum*.  
Small strongyles including those resistant to some benzimidazole class compounds (adults and 4<sup>th</sup> stage larvae):  
*Coronocylus* spp. including: *C. coronatus*, *C. labiatus*, *C. labratus*; *Cyathostomum* spp. including: *C. catinatum*, *C. pateratum*; *Cylicocyclus* spp. including: *C. insigne*, *C. leptostomum*, *C. nassatus*, *C. brevicapsulatus*; *Cylicodontophorus* spp.; *Cylicostephanus* spp. including: *C. calicatus*, *C. goldi*, *C. longibursatus*, *C. minutus*; *Petrovinema poculatum*.  
Pinworms (adults and 4<sup>th</sup> stage larvae) - *Oxyuris equi*  
Ascarids (adults and 3<sup>rd</sup> and 4<sup>th</sup> stage larvae) - *Parascaris equorum*  
Hairworms (adults) - *Trichostrongylus axei*  
Large-mouth stomach worms (adults) - *Habronema muscae*  
Bots (oral and gastric stages) – *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*  
Lungworms (adults and 4<sup>th</sup> stage larvae) - *Dictyocaulus arnfieldi*  
Intestinal threadworms (adults) - *Strongyloides westeri*  
Summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

Exclusivity: 3 years

21CFR 520.1198

## Actions Taken by FDA Center for Veterinary Medicine

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### ANADA Number: 200-319

Pioneer Product: 015-030  
Trade Name: Acepromazine Maleate Injection  
Ingredients: Acepromazine maleate  
Sponsor: Phoenix Scientific, Inc.  
Approval Date: March 25, 2003  
Status: Prescription only  
Route: Intravenous, intramuscular, or subcutaneous  
Species: Dogs, cats, and horses  
Drug Form: Liquid (solution)  
Concentration: 10 milligrams per milliliter  
Indications: Used as a tranquilizer.

21CFR 522.23

### ANADA Number: 200-350

Pioneer Product: 129-831  
Trade Name: Exodus<sup>TM</sup> Paste  
Ingredients: Pyrantel pamoate  
Sponsor: Cross Vetpharm Group Ltd.  
Approval Date: March 25, 2003  
Status: Over-the-counter  
Route: Oral  
Species: Horses  
Drug Form: Paste  
Concentration: 171 milligrams pyrantel base as pyrantel pamoate per milliliter of paste  
Indications: For the removal and control of infections from the following mature parasites: large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equines*); small strongyles; pinworms (*Oxyuris equi*); and large roundworms (*Parascaris equorum*).

21CFR 520.2044

## Supplemental Approvals

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### NADA Number: 131-675

**This supplemental application provides for use of an approved Type A Medicated Article to make Type B and Type C medicated feeds used for the control of gastrointestinal worms in horses.**

Trade Name: Safe-Guard<sup>®</sup> Dewormer 20% Type A Medicated Article  
Ingredients: Fenbendazole  
Sponsor: Intervet, Inc.  
Approval Date: March 14, 2003  
Status: Over-the-counter  
Route: Oral, via feed  
Species: Horses  
Drug Form: Type A Medicated Article to make Type B and C medicated feeds.  
Concentration: 90.7 grams fenbendazole activity per pound of Type A Medicated Article  
Indications: For control of large strongyles (*Strongylus edentatus*, *S. equines*, *S. vulgaris*, *Triodontophorus* spp.); small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.); pinworms (*Oxyuris equi*); and ascarids (*Parascaris equorum*).  
Exclusivity: 3 years

21CFR 558.258

## Actions Taken by FDA Center for Veterinary Medicine

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**NADA Number: 141-199**

**This supplemental application provides for a once daily subcutaneous injection of carprofen solution for the relief of pain and inflammation associated with osteoarthritis.**

Trade Name: Rimadyl® Injectable  
Ingredients: Carprofen  
Sponsor: Pfizer, Inc.  
Approval Date: March 25, 2003  
Status: Prescription only  
Route: Subcutaneous  
Species: Dogs  
Drug Form: Liquid (solution)  
Concentration: 50 milligrams per milliliter  
Indications: For the relief of pain and inflammation associated with osteoarthritis.  
Exclusivity: 3 years

*21CFR 522.312*

**NADA Number: 096-298**

**This supplemental application provides for the use of a lasalocid Type A Medicated Article to make free-choice loose mineral Type C medicated feeds.**

Trade Name: Bovatec® 68 Type A Medicated Article  
Ingredients: Lasalocid  
Sponsor: Alpharma, Inc.  
Approval Date: April 9, 2003  
Status: Over-the-counter  
Route: Oral, via feed  
Species: Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers)  
Drug Form: Type A Medicated Article to make Type C medicated feed.  
Concentration: 68 grams lasalocid activity per pound or Type A Medicated Article  
Indications: For increased rate of weight gain.  
Tolerance: *21CFR 556.347* Lasalocid: A tolerance is established for residues of 0.7 part per million for parent lasalocid in liver (target tissue). An acceptable daily intake (ADI) of 0.01 milligram per kilogram of body weight per day for lasalocid is established.  
Withdrawal: Zero days  
Exclusivity: 3 years

*21CFR 558.311*

## Change of Sponsor's Name

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From: Fort Dodge Animal Health, Division of American Cyanamid Co.  
To: Fort Dodge Animal Health, Division of Wyeth Holdings Corp.

## Actions Taken by FDA Center for Veterinary Medicine

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### Change of Sponsor

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**NADA Number: 005-236**

From: Combe, Inc.  
To: Farnam Companies, Inc.  
301 West Osborn  
Phoenix, AZ 85013-3928  
Drug labeler code: 017135

**NADA Number: 065-505, 065-506, 049-187, 122-447, 130-136, 140-582**

From: Anthony Products Co.  
To: Cross Vetpharm Group Ltd.  
Broomhill Rd.  
Tallaght, Dublin 24  
Ireland  
Drug labeler code: 061623

### Suitability Petition Action

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Number: 03P-0219/CP1  
Sponsor: Vetoquinol N.-A. Inc.  
Petition: Request permission to file an ANADA for a generic new animal drug, amoxicillin, which differs from the pioneer product, Robamox<sup>®</sup>-V (amoxicillin trihydrate), Teva Pharmaceuticals USA, NADA 065-495, by the following characteristics: The generic product will have a different dosage form (paste) and strength from the pioneer.  
Action: Filed on May 19, 2003.

Number: 03P-0108/CP1  
Sponsor: Cross Vetpharm Group, Ltd.  
Petition: Request permission to file an ANADA for a generic new animal drug apramycin which differs from the pioneer product, Apralan<sup>®</sup> (apramycin sulfate), Elanco Animal Health, NADA 106-964, by the following characteristic: The generic product will have a different excipient and strength from the pioneer.  
Action: Approved on June 4, 2003.

Number: 03P-0223/CP1  
Sponsor: Richdel, Inc.  
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan<sup>®</sup> (ivermectin) Liquid for Horses, Merial Ltd., NADA 140-439 by the following characteristic: The generic product will have a different dosage form (solubilized gel) from the pioneer.  
Action: Filed on May 23, 2003.

### Technical Amendment

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When the name of Fort Dodge Animal Health, Division of American Home Products Corp. was changed to Fort Dodge Animal Health, Division of Wyeth (67 FR 67520, November 6, 2002) an inaccurate correction to the address was made. At this time, it is being changed to the original and correct address in section 510.600.